

rejection, In re Schneller found at 158 USPQ 210 (CCPA 1968), and further cites Section 804 from the Manual of Patent Examining Procedure.

As described in Section 804 of the Manual, In re Schneller involved an initial patent application describing, as a preferred embodiment, an invention involving a combination and two further inventions involving subcombinations. Prosecution and examination resulted in this initial application issuing as a patent with claims drawn to one of the subcombinations. A divisional application was also filed after the filing of, and to co-pend with, the initial patent application with this divisional application having claims directed to the other subcombination and to the preferred embodiment combination. The court sustained a rejection of the divisional application on grounds of double patenting without finding that claims directed to the subcombination and combination therein were obvious over the subcombination claimed in the issued patent because the preferred embodiment combination, disclosed in both the issued patent and the divisional application and covered by the claims of the patent, would have had the patent rights thereto extended by allowance of the claims in the divisional application.

In contradistinction, although the preferred embodiment of the present application is described therein and in each of the above listed patents, only the claims in this application and in U.S. Patent 5,533,499 are directed to a form of that preferred embodiment. The claims in the remaining patents from the above listing, U.S. Patents 5,476,091; 5,533,503 and 5,549,103, are directed to combinations that may involve this preferred embodiment but clearly claim at least one further element in each. Thus, the claims in these last three patents are not directed to the preferred embodiment of the present application through claiming common subject matter as in In re Schneller, but instead clearly claim narrower subject matter. In these circumstances, the applicant is enclosing a Terminal Disclaimer for the present application with respect to only U.S. Patent 5,533,499 in view of the claims in the other above listed patents not being directed to the subject matter of this application.

The Examiner then goes on to object to the specification under 35 U.S.C. § 112 as not providing support for claim 8 insofar as the original disclosure in the specification only disclosing, as the preferred embodiment, a nasal dilator without disclosing other uses for that

dilator. In view of this alleged lack of support, the Examiner has also rejected claim 8 under 35 U.S.C. § 112 as being inadequately supported by the specification. In summary, the Examiner appears to find, that out of the set of dilators for use in dilating all other possible portions of human anatomy, only the subset of dilators used for dilating noses is disclosed thus providing inadequate support for claiming dilators other than just nasal dilators.

The applicant readily concedes that the dilator disclosed in the present application has been disclosed therein as having a preferred embodiment suiting it for use in dilating the outer wall tissues of the nasal passages, and without any further showing of using the dilator disclosed for dilating other portions of human anatomy. Yet, the resulting dilation of intervening bodily tissues located between the dilator ends is clear and inherent wherever the dilator of the present invention is flexed while having its ends engaged with human anatomy tissue. The sufficiency of a single embodiment in predictable technology applications, such as mechanical device applications, is well established. In such circumstances of inherent abilities in the invention for use on human anatomy, the applicant clearly has a right to claim the dilator of his invention no matter what new locations on a human anatomy users may chooses to engage the dilator beyond the example use given in the disclosed preferred embodiment involving the human nose. Surely there is no requirement to show use of the dilator of the present invention on every portion of a human anatomy where it can be used as a basis for supporting an apparatus claim drawn to the dilator of the present invention.

The Examiner next rejects claims 1 through 22 under 35 U.S.C. § 112 as being indefinite in several instances. In the first instance, the Examiner points out that claim 1 lacks an antecedent basis for the phrase "the deformable means" appearing in the third line of the last paragraph therein. The applicant has amended claim 1 to replace this phrase in a manner consistent with the remainder of the paragraph, and so believes that this rejection has been overcome.

The Examiner then questions the nature of the phrase "the inherent tendency of the truss member to return to its normally planar state ... drawing in during breathing" appearing in the second to the last paragraph of claim 1. The phrase describes the result in use of a

property of the defined unitary truss member, and the following paragraph of the claim, after the above amendment, sets forth a structural arrangement involving the "resilient member" that provides that property. Thus, this phrase is not a Section 112, 6th paragraph limitation as it depends instead on the well known nature of resilient structures, see Greenberg v. Ethicon Endo-Surgery Inc., 39 USPQ2d 1783 (Fed. Cir. 1996).

The Examiner then asks about the support in the specification for the phrase "a resilient member" in the last paragraph of claim 1 in view of claim 2, dependent on claim 1, reciting "a resilient means" in the second paragraph thereof. The applicant inadvertently failed to change claim 2 to be in accord with claim 1, and has now done so by the above amendment to correct this inconsistency by changing claim 2 to match the phrasing of claim 1 in referring to a resilient band and adhesive strip in the invention.

The Examiner then goes on to question whether the last paragraph of claim 1 is a Section 112, 6th paragraph limitation, and apparently whether claim 6 is such a limitation. As explained above, neither of the last two paragraphs of claim 1 is a Section 112, 6th paragraph limitation. Claim 6 is not such a limitation either as it merely sets forth the orientation of a band in allowing its resiliency to provide the unitary truss member tendency property.

The Examiner then requires to whether the last paragraph of claim 8 is a Section 112, 6th paragraph, limitation. That paragraph is such a limitation in accord with the Greenberg decision cited above.

This same inquiry is put by the Examiner with respect to claim 9. Claim 9 is not such a limitation as it merely sets forth the degree of the recited restoring forces required to be present in the single body truss.

In a further question with respect to claim 10, the Examiner asks whether the phrases "a resilient means" and "a deformable means" refer to the same elements. The applicant has inadvertently included "resilient means" rather than --resilient member-- in claim 10 but has used the above amendment to correct this inadvertence, as elsewhere in the claims, as appropriate. The applicant cannot find the phrase "deformable means" used in claim 10, although the phrase "a deformable material" has been used in that claim. The resilient member phrase refers to the

band while the deformable material phrase can refer to an adhesive or a flexible fabric strip, or both.

Finally, the Examiner points out that there is a lack of a proper antecedent for the phrase "said spacing reduction forces" used in two places in claim 13. The applicant believes the above amendment has removed this inconsistency.

The Examiner then rejects claims 1, 3, 8 through 11, 13 through 15, 17, 20 and 22 under 35 U.S.C. § 103 as being obvious in the face of U.S. Patent 1,292,083 to Sawyer. The Examiner appears to contend that the Sawyer dilator, formed by an assembly of spring member 7 with hooks on either end thereof to be used in hooking that end to a corresponding one of a pair of loop 6 and pad 5 combinations as shown in Figure 2 thereof, provides the unitary truss member of claim 1. This apparently particularly follows from the Examiner's finding of no difference between the Sawyer dilator spring being bent from its curved, force free (or natural) state and the bending of the truss member of claim 1 from its normally planar state, except for the substitution of a known spring material for the Sawyer spring member in the structure primarily being bent. With this contention, the applicant must respectfully disagree.

At the outset, the Sawyer reference dilator is not a unitary truss as shown in Figure 2 of that reference. The dilator shown in Figure 2 is stated in the Sawyer reference to be shown there in "assembled condition" at lines 45 and 46 on the first page of that reference. The Webster Third New International Dictionary defines "assemble" as to "fit together the various parts of so as to make into an operative whole" clearly indicating that the dilator pictured in Figure 2 of the Sawyer reference is a whole formed of various parts. In contrast, the word "unitary" is defined in that dictionary as something having the "character of a unit: not divided or discontinuous" clearly negating the presence of assembled parts.

These differences in the meaning of the words "assembled" and "unitary" are fully reflected in the differences between the Sawyer reference dilator and the dilator of the present invention. The Sawyer reference dilator is shown to be formed of several easily assembled and disassembled parts. This characteristic of the Sawyer reference dilator is fundamental thereto since the user, to obtain the full operative value from that dilator, must be able to engage spring

member 7 with loops 6, and then be able to disengage that spring from those loops after the pads have been mounted on the user's nose, for purposes of spring force adjustment. The present invention, on the other hand, has all portions thereof bound to one another to form a continuous whole, that is, a single body, without provision for any adjustment after being mounted on a user's nose.

Further arguing against the Examiner's contention is that there is, indeed, a great difference between i) the truss of the present invention having an inherent tendency to return to the normal planar state to thereby result in a restoring force occurring therein after flexure, and ii) the tendency of the Sawyer reference dilator spring member to return to its natural, or force free state, after being bent away therefrom. The tendency of the dilator of the present invention to return to a planar state after being flexed results in a relatively uniform restoring force in the outward direction over the angular range, or extent, of flexure to the full 180 degrees possible so as to result in no need for adjustment in the amount of restoring force. The Sawyer reference dilator, on the other hand, must provide an adjustment to the restoring force provided by the spring wire used in a bent natural state because the further bending from that natural state provides a continually increasing magnitude restoring force (with the rate of increase set by the effective spring constant) over a relatively short angular range until a plastic yield point is reached, and provides this force in a direction which depends on the direction of the further bending from the natural state. Such rapidly increasing magnitude spring forces, in each of different possible directions, requires the natural state bend in the spring wire curve to be adjusted to provide an acceptable restoring force for the user. This is done by bending the metal of the wire at the natural state bend to the point of the metal plastically yielding to change the natural state bend as the adjustment.

Finally, with regard to the Examiner's contention above, the applicant's resilient member does not merely represent the mere substitution of the known spring material thereof for that of another spring referring to the spring wire of the Sawyer reference dilator. On the one hand, the resilient member of the dilator of the present invention replaces at the very least spring wire 7 and loops 6 of the Sawyer reference. In doing so, a second mode of adjustment used with

the Sawyer reference dilator is completely eliminated, i.e. the plurality of bent or hooked portions in spring wire 7 provided to allow different ones thereof to engage loop 6 for purposes of accommodating differently sized noses is eliminated. In addition, as just described above, the much different character of the resiliency found in the resilient band in the dilator of the present invention compared to that found in the spring wire in the Sawyer reference has allowed eliminating the first mode of adjustment used with the Sawyer reference dilator involving passing the plastic yield point of the spring wire used therein. Such a replacement of multiple structures by one structure exhibiting a significantly different behavior than those multiple structures is far from a mere substitution of one known material for another.

The overwhelming advantages for the user provided by these differences between the dilator of the present invention and the Sawyer reference dilator comes about because of the much greater convenience that results from their presence. Rather than the individual attachment of pads to the user's nasal passages followed by a series of adjustment manipulations as envisioned with the Sawyer reference dilator to permit its assembly in situ on the user's nose, the single body, adjustment free dilator of the present invention is merely easily pressed into position on the user's nose. There is no subsequent concern that the mere bumping of the dilator, or the simple pressing the user's nose into a pillow, could result in disconnecting a wire having a relatively sharp end that could later inadvertently wind up being pressed into a user's body injuring him or her as there is with the Sawyer reference dilator. The economic cost to manufacture and distribute the dilator of the present invention compared to that for the Sawyer reference dilator is much less because of the present dilator being conveniently suited for available high volume manufacturing and packaging processes.

These advantages are apparently well recognized. Since the introduction into the United States marketplace of external nasal dilators based on the present invention, several other external nasal dilators were later introduced into these same markets as competing products as set out in the accompanying declaration of the chief executive officer of the licensee of the applicant's assignee. No markets were in existence at all for external nasal dilators prior to the marketing of such dilators based on the applicant's invention by the licensee of the applicant's

assignee, apparently because no such external nasal dilator products had been available prior to such marketing. Yet, despite the Sawyer reference dilator construction having been available free for anyone to use for over fifty years, not only were there no external nasal dilator products offered for sale prior to those offered by the licensee of the applicant's assignee, but every one of those competing nasal dilators subsequently offered for sale in the marketplace used one or more resilient members which tended to return to a normal planar state following flexure thereof. That is, as set out in the accompanying declaration, apparently not a one of the later introduced competing nasal dilator products been based on the multiple body dilator technology of the Sawyer reference using a wire as a connecting spring (and as a connector in the Figure 2 assembly of that reference), a technology that was easily understood and freely available from that now expired patent. Such competitor recognition of the advantages of the dilators of the present invention over the Sawyer reference dilators argues very strongly the patentability of the present invention over the Sawyer disclosure.

That the advantages of the applicant's external nasal dilator construction over the Sawyer reference construction can deservedly be called "overwhelming", as stated above, is conclusively further supported by the tremendous success in the U. S. marketplace of dilator products based on the applicant's invention. Starting from no market for external nasal dilators in 1993 and with no paid advertising having been used to offer such external nasal dilators for sale, the licensee of the applicant's assignee had commercial orders for, and delivered, more than one million units of external nasal dilator products coming within the claims of this application as set out in the accompanying declaration. By the start of 1995, with relatively small expenditures for advertising, orders and deliveries for such products had exceed one million units per month. Despite such advertising being directed toward medical uses, sports enthusiasts as well as professional athletes had begun by then to use the product.

Subsequently, during 1995, nearly one hundred fifty million such dilators were delivered to customers of the licensee. Now to date in 1996, sales and deliveries of the applicant's invention within the scope of the claims of the present invention have already substantially exceeded 1995 deliveries, and have been accompanied by rapidly increasing sales

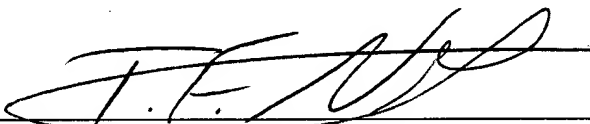
in foreign countries as consumers there, just as eagerly as here in the United States, opted for the advantages and benefits provided by these products. Yet again, despite such market success for external nasal dilators, not one product based on the freely available technology in the Sawyer reference is known to have come to market. Such a history of consumer acceptance strongly demonstrates the patentability of the unitary or single body external nasal dilator of the present invention over the multiple part construction of the Sawyer reference dilator that permits assembly and disassembly thereof to satisfy its adjustment requirements.

The applicant notes that the Examiner would allow claims 2, 4 through 7, 12, 16, 18, 19 and 21 if suitably rewritten. In view of the applicant's belief that the remaining claims in the present application are also allowable as demonstrated above, the applicant will not rewrite these claims at this time for this purpose but stands ready to do so if that course should become appropriate.

In view of the foregoing, the applicant respectfully requests the Examiner reconsider her rejection of the claims as amended, and further requests these claims as amended now be allowed.

Respectfully submitted,

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